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## CASSETTE FOR INTRAVENOUS-LINE FLOW-CONTROL SYSTEM

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### DESCRIPTION

#### Related Applications

10 The present application is a continuation of U.S. application serial No. 08/917,537  
filed August 22, 1997, which, in turn, is a continuation-in-part of U.S. application serial  
no. 08/478,065 filed June 7, 1995, <sup>now U.S. Patent No. 6,165,154,</sup> which issued as U.S. Patent No. 5,755,683 on May 26,  
1998, which was concurrently filed with applications serial no. 08/472,212, entitled  
"Intravenous-Line Flow-Control System" for an invention by Heinzmann, Kamen,  
Lanigan, Larkins, Lund and Manning, which issued on June 30, 1998 as U.S. Patent No.  
15 5,722,637; serial no. 08/481,606, entitled "Intravenous-Line Air-Elimination System" for  
an invention by Manning, Larkins, Houle, Kamen and Faust, which issued on February 3,  
1998 as U.S. Patent No. 5,713,865; and serial no. 08/477,380, entitled "Intravenous-Line  
Air-Detection System" for an invention by Larkins, Beavis and Kamen, which issued on  
June 24, 1997 as U.S. Patent No. 5,641,892. All of these related applications are hereby  
20 incorporated herein by reference.

#### Technical Field

The present invention relates to apparatus and methods for controlling flow  
through an intravenous line.

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#### Summary of the Invention

The invention is directed to a cassette for controlling the flow of IV fluid from a  
patient to a source. The cassette preferably includes, along the fluid passage through the  
cassette, first and second membrane-based valves on either side of a pressure-conduction  
30 chamber, and a stopcock-type valve. The stopcock valve is preferably located  
downstream of the second membrane-based valve, which is preferably located  
downstream of the pressure-conduction chamber.

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In a preferred version of the cassette, which is primarily made out of rigid material, the membrane for the second membrane-based valve is disposed adjacent the housing, such that the rigid housing and the membrane define a valving chamber. One passage enters the valving chamber at a first mouth located at the end of a protrusion of the rigid housing into the valving chamber towards the membrane, and the valve may prevent the flow of fluid therethrough when the membrane is forced against the first mouth, by the control unit. The control valve restricts the flow of intravenous fluid from the valving chamber to the patient, since it is located downstream of the valving chamber. The membrane defining the valving chamber is preferably large and resilient, so that the valving chamber may provide a supply of pressurized intravenous fluid to the patient, when the first mouth is sealed closed and when there is a restriction downstream of the valving chamber.

For the pressure-conduction chamber, a membrane is preferably disposed adjacent the rigid housing, so as to define a pressure-conduction chamber, wherein the rigid housing portion that defines the pressure-conduction chamber is generally dome-shaped. The membrane has a filled-chamber position, in which position the pressure-conduction chamber is substantially at its greatest volume, and an empty-chamber position, in which position the pressure-conduction chamber is at its smallest volume, and in which position the membrane rests against the rigid housing and assumes the dome shape of the rigid housing. The membrane preferably has a structure for creating instability in the membrane in the filled-chamber position. Preferably, this structure may be actuated to create instability in the membrane in the empty-chamber position. The rigid housing and the second membrane in the empty-chamber position preferably define an unobstructed fluid passageway through the pressure-conduction chamber from the first to the second pressure-conduction chamber mouth. Preferably, the structure for creating instability in the membrane causes the membrane, when its at its full-chamber position, to collapse in the region of the pressure-conduction chamber's outlet mouth before collapsing nearer the inlet mouth. This structure helps force bubbles in the fluid upward toward the inlet mouth and the IV fluid source during a bubble-purge cycle.

#### Brief Description of the Drawings

FIG. 1 shows a top view of a cassette according to a preferred embodiment of the

present invention.

FIGS. 2 and 3 show front and bottom views respectively of the cassette of FIG. 1.

FIG. 4 shows a control unit for receiving and controlling a cassette, such as the cassette of FIGS. 1 - 3.

5 FIG. 5 shows a cross-section of the cassette of FIGS. 1 - 3.

FIG. 6 shows a rear view of the cassette and shows the fluid paths through the cassette.

FIG. 7 shows a front view of the middle rigid panel of the cassette of FIGS. 1 - 3.

FIGS. 8 and 9 show side and rear views respectively of the middle panel of FIG. 7.

10 FIG. 10 shows a partial cross-section of the middle panel of FIG. 7.

FIG. 11 is a cross-sectional detail of the control valve of the cassette according to a preferred embodiment of the invention.

FIG. 12 shows a side view of an outer cylinder (a valve-seat member) having rigid and resilient elements that may be used in the control valve.

15 FIG. 13 shows a cross-sectional view of the cylinder of FIG. 12.

FIG. 14 depicts the relationship between the aperture of the FIG. 12 cylinder and the groove used in the control valve.

FIG. 15 shows a cross-sectional view of the membrane that may be used in the pressure-conduction chamber of the cassette shown in FIG. 1.

20 FIGS. 16 and 17 show front and rear views respectively of the FIG. 15 membrane.

FIG. 18 shows a front view of the membrane used in the valve located downstream of the pressure-conduction chamber and upstream of the control valve.

FIG. 19 shows a cross-section of the FIG. 18 membrane.

25 FIG. 20 is a schematic representing how the compliant membrane of FIG. 18 may be used to regulate the pressure of fluid to the patient.

FIG. 21 is a graph depicting the advantage of using a compliant membrane such as that shown in FIG. 18.

FIGS. 22 and 23 depict the preferred shape of the inlet valve to the pressure conduction chamber.

30 FIG. 24 shows a cross-sectional view of the inlet valve to the pressure conduction chamber.

FIG 25 shows a preferred arrangement of teeth around the circumference of the

control wheel.

FIG. 26 shows a front view of a cassette according to an alternative preferred embodiment of the present invention.

FIG. 27 shows a front view of the membrane that may be used in the pressure-  
5 conduction chamber of the cassette shown in FIG. 26.

FIG. 28 shows a cross-sectional view of the membrane shown in FIG. 27 along

line B-B.

*Fig 29 shows another cross-sectional view of the membrane shown in Fig. 27.*

FIG. 30 shows a cross-sectional view of the membrane shown in FIG. 27 along  
line A-A.

FIG. 31 shows a perspective view of an alternative cassette which may use the  
10 membrane shown in FIGS. 27-30.

#### Detailed Description of Specific Embodiments

15 The present invention includes a cassette for use in a system for controlling the flow of IV fluid to a patient, along the lines of the cassettes disclosed in U.S. Patents Nos. 5,088,515 and 5,195,986. A preferred embodiment of the cassette is depicted in FIGS. 1 - 3, which respectively depict top, front and bottom views of the cassette. The cassette is used in a control unit, such as that described in above-referenced U.S. Patent No.  
20 5,772,637, entitled "Intravenous-Line Flow-Control System," which is similar to the control unit described in U.S. Patent No. 5,088,515, which describe the use of pressure, preferably pneumatic pressure, for controlling the actuation of valves and the urging of fluid into and out of a pressure-conduction chamber. In addition to performing the function of a pump urging fluid through the IV line, the pressure-conduction chamber can  
25 measure the amount of IV fluid being delivered to the patient as well as detect the presence of bubbles in the IV fluid in the pressure-conduction chamber. Preferred methods of detecting and eliminating air bubbles from the IV fluid are discussed in the above-referenced patent applications for "Intravenous-Line Air-Detection System" and "Intravenous-Line Air-Elimination System," now U.S. Patent Nos. 5,641,982 and  
30 5,713,865, respectively. FIG. 4 depicts a preferred version of a control unit 10. Control unit 10, which has a user-interface panel 103 containing a key pad and a display so that the status of the IV fluid delivery may be monitored and modified by medical personnel.

The cassette is slipped behind door **102**, and by turning handle **101** the door is pressed against the cassette, which in turn is then pressed against the main housing of the control unit **10**. The main housing **104** preferably includes mechanical means for actuating membrane-covered valves and for applying a pressure against the membrane of the pressure-conduction chamber. The main housing **104** also includes means for turning the control wheel of the cassette.

Referring to FIG. 2, the main components of the preferred embodiment of the cassette are a first membrane-based valve **6**, a pressure-conduction chamber **50**, a second membrane based valve **7** and a stopcock-type control valve **20**. Valve **6** controls the flow to the pressure-conduction chamber **50** from the inlet **31** to the cassette, which is connected to an IV line, which in turn is connected to a source of IV fluid. The second membrane-based valve **7** and the control valve **20** together are used to control the flow of fluid from the pressure-conduction chamber **50** to the outlet to the cassette **33**, which is connected to the IV line leading to the patient.

The rigid housing **15** of the cassette is made primarily from three rigid panels. A front panel **17**, a middle panel **18**, and a rear panel **16**, all three of which can be seen in FIGS. 1 and 3. The front panel is preferably molded integrally with the outer collar **21** of the control valve **2**. The wheel **20** of the control valve **2** preferably includes ribs **281** and/or teeth mounted along the circumference **29** of the knob **20**. (FIG. 25 shows a preferred arrangement of teeth around the circumference **29** of the control knob **20**.) The teeth and/or ribs **281** may be engaged by the main housing **104** of the control unit **10**, so that the control unit **10** may change the resistance that the control valve **2** exerts on the IV fluid passing through the valve.

The cassette may also be used without the control unit **10**. In that case, the control wheel **20** may be turned by hand. When disengaged from the control unit **10**, the membrane of the pressure-conduction chamber **50** is preferably collapsed so that it rests against the rigid rear wall **59** of the pressure-conduction chamber **50**. With the membrane in this collapsed state, IV fluid may still easily flow through the pressure-conduction chamber **50** through a raised portion **35** of the rear wall **59**. This raised portion **35** defines a conduit **36** leading from the inlet mouth of the pressure-conduction chamber **50** to the

outlet mouth of the pressure-conduction chamber, as can be seen in FIG. 6. FIG. 6 shows the fluid paths leading through the cassette. As noted above, fluid enters the cassette through the inlet 31, whence it flows through a fluid path to valve 6. The fluid then enters the valving chamber of valve 6 through an inlet port 62. An outlet port 61 is preferably mounted on a protrusion so that pressure from the pressure-conduction chamber 50 is less likely to force the membrane to lift from the outlet port 61. From valve 6 the fluid passes to the inlet mouth 56 of the pressure-conduction chamber 50. The pressure-conduction chamber is seen in the cross-sectional view of FIG. 5. A membrane 41 allows pressure from the control unit 10 to be applied to the fluid in the pressure-conduction chamber 50 without the fluid coming into contact with the control unit 10. When the membrane 41 is in its collapsed position resting against rigid wall 59, as shown in FIG. 5, fluid can still pass from inlet valve 56 through conduit 36 to the outlet valve 57. After passing through the pressure-conduction chamber 50, the fluid flows to the second membrane-based valve 7, which included an inlet mouth 73, which is mounted on a protrusion 72 in similar fashion to the outlet port 61 of the first membrane-based valve 6. The second membrane-based valve's inlet mouth 73 and the protrusion 72 on which it is mounted can be seen in the cross-sectional view of FIG. 5. Like the outlet port 61 of the first membrane-based valve, the inlet mouth 73 may be closed by the application of pressure by the control unit 10 on a membrane; a first portion 71 of the membrane that closes off the inlet mouth 73 can be seen in FIG. 5. After passing through the outlet mouth 76 of the second membrane-based valve 7, the fluid passes to the inlet 77 of the stopcock-type control valve, which inlet can be seen in both FIGS. 5 and 6. After passing through the control valve and the fluid path 78 exiting from the control valve, the fluid passes to the outlet of the cassette 33 and to the IV line leading to the patient.

FIG. 7 shows a front view of the rigid middle portion of the cassette, and FIG. 8 shows a side view of the middle rigid panel 18. The middle rigid panel 18 defines the cassette inlet 31 and outlet 33, a circumferential portion of the pressure-conduction chamber 50, and port 62, outlet port 61, inlet mouth 73, and outlet mouth 76 of the two membrane-based valves 6 and 7. The protrusions 63 and 72 of the outlet port 61 and inlet mouth 73 can also be seen in FIG. 7. FIG. 9 shows a rear view of the middle rigid panel

18 shown in FIGS. 7 and 8. The ports/mouths **61, 62, 73, 76** can also be seen in FIG. 9. FIG. 10 shows a partial cross-section of the middle rigid portion. The cross-section shows the outer collar **21** of the control valve, which is integrally molded with the rest of the middle rigid portion. The outer collar **21** defines a hollow area **22** and a fluid path **23** leading from the hollow area **22**.

FIG. 11 shows a cross-section of an assembled control valve **2** that may be used in a cassette according to the present invention. Just inside of the outer collar **21** is a valve-seat member **22** fixedly attached to the outer collar **21** so that the valve-seat member **21** does not rotate with respect to the rest of the cassette. The valve-seat member **21** is depicted in greater detail in FIG. 12 and in cross-section in FIG. 13. The valve-seat member **22** also defines a hollow area, which accepts the shaft **220** of the control wheel **20**, so that the control wheel's shaft **220** rotates with the control wheel **20**. The valve-seat member **22** is comprised mostly of rigid material, but importantly it also includes molded-over resilient material, which is used to form sealing O-rings. This resilient material forms an O-ring **26** around the base of the valve-seat member **22**; the rigid portion of the base defines a passage **222**, connecting the valve inlet **77** to passage **24**. The resilient material **25** also provides a seal around an aperture **251** in the circumferential surface of the member **22**. At the end of the member **22** opposite the inlet passage **222** is an inner O-ring **27** which forms the seal between the control wheel's shaft **220** and the valve-seat member **22**. The O-ring **26** around the exterior circumference of the base provides a seal between the outer circumferential wall of the valve-seat member **22** and the inner circumferential wall of the outer collar **21**. Likewise, the O-ring **25** around the circumferential port **251** may provide a seal between the outer circumferential wall of the valve-seat member **22** and the inner circumferential wall of the outer collar **21**. Together, O-rings **25, 26** prevent fluid from leaking between the valve-seat member **22** and the outer collar **21**. Importantly, the O-ring **25** of port **251** also provides a seal between the valve-seat member **22** and the shaft **220**, so that when the valve is in the fully closed position no flow is permitted between passageway **24** of shaft **220** and the port **251** of the valve-seat member **22**.

The advantage of this design over previous stopcock valves is that the outer

diameter of the shaft **220** may be slightly less than the inner diameter of the valve-seat member **22**, whereas previous stopcock valves required an interference fit between the inner and outer components. It will be appreciated that the stopcock valve of the present invention may use frusto-conical-shaped members instead of cylindrical members. The interference fit of prior-art devices created a great deal of resistance when the stopcock valves were turned. The use of O-rings in the stopcock valve of the present invention avoids the need for this interference fit and the greater torque required for turning the valve resulting from the interference fit. O-ring **27** prevents leaking from the space between the valve-seat member **22** and the shaft of the control wheel **20**.

10       The valve-seat member is preferably made in a two-part molding process, wherein the rigid portion is first molded and then the softer resilient material is over-molded onto the rigid portion. Channels may be provided in the initially molded rigid portion so that the resilient material may flow to all the desired locations; this results in columns of resilient material **28** connecting the areas of resilient material through these channels.

15       The valve-seat member **22** is preferably molded separately from the rest of the cassette, and when the cassette is assembled the valve-seat member **22** is placed in the hollow defined by the outer collar **21** of the middle panel **18**, and aligned so that aperture **251** lines up with passageway **23**. (The shape of the outer diameter of the valve-seat member **22** and the inner diameter of the outer collar **21** may be complementarily shaped so that

20       the valve-seat member must align properly with the aperture **251** and the passageway **23** lined up.) Then, the front rigid panel **17** is ultrasonically welded (along with the rear rigid panel **16**) to the middle rigid panel **18**, and the valve-seat member **22** is then held in place in the hollow area defined by the outer collar **21**. The outer circumference of the valve-seat member **22** may be a bit smaller than the inner diameter of the outer collar **21**; O-

25       rings **25**, **26** prevent fluid from flowing from the passages **77** or **23** to point **19**. This design of the valve-seat member **22** avoids the need for tight tolerances in the various components of the valve **2**. The control wheel's shaft **220** may be inserted into the hollow area defined by valve-seat member **22** after the rest of the valve has been assembled. The shaft **220** is held in place by a lip **161** around the inner circumference of the hollow area

30       defined by the rear rigid panel **16**

When the valve **2** is fully opened, the circumferential aperture **251** is lined up with



the fluid passage 24 in the shaft 220. When the valve is fully closed there is no fluid communication between the aperture 251 and the fluid passage 24. The outer circumferential surface of the shaft 220 preferably includes a groove extending circumferentially around the shaft's outer circumferential wall from the terminus of the fluid passage 24 at the outer circumferential wall; the groove tapers in cross-sectional area and does not extend all the way around the outer circumference of the shaft 220. The groove provides greater control of the flow rate. FIG. 14 shows the respective locations of the groove 231, which is located on the outer circumference of the shaft 220 and the circumferential aperture 251 of the valve seat member 22. As the aperture 251 rotates to the right, in the FIG. 14 perspective, the resistance to flow increases, until the groove 231 ends and the aperture 251 loses fluid communication with the groove 231, at which point flow is completely shut off through the control valve 2. As the aperture 251 rotates to the left, in the FIG. 14 perspective, the resistance to flow decreases. Preferably, the groove 231 is longer than the diameter of the aperture 251, so that the flow rate may be controlled more finely.

As noted above, the cassette may be used independently of the control unit 10. When the cassette is used in this manner it is preferable that the membrane 41 rest against the rigid back 59 of the pressure-conduction chamber 50 so as to minimize the volume of the conduit 36 for fluid passing through the pressure conduction chamber 50. If the membrane 41 were too flexible and the volume of the pressure-conduction chamber 50 varied widely, medical personnel would be unable to rely on a quick visual inspection of the rate of dripping in the drip chamber to indicate a steady, desired flow rate through the IV line. Thus, it is desired that the structure of the membrane 41 be such that it tends to rest against wall 59 unless and until a sufficient pressure differential is created across the diaphragm 41. This pressure differential is preferably caused by a negative gas pressure caused by the control unit 10. Although it is desired to manufacture the diaphragm 41 so that it has some tendency to rest against wall 59, it is desired to make the diaphragm 41 floppy in the other direction so that less pressure is required to move it from its position when the pressure-conduction chamber 50 is full, the "filled-chamber" position. It is also desired that the measurement gas provided by the control unit 10 against the outer face of

the membrane **41** be at substantially the same pressure as the fluid on the inner side of the membrane **41** in the pressure-conduction chamber **50**.

By molding the diaphragm **41** in the shape of a dome corresponding to that of the rigid wall **59**, the diaphragm will have a tendency to remain in its position, as shown in  
5 FIG. 5, resting against wall **59** when the chamber **50** is at its lowest volume, the "empty-chamber" position. However, when the diaphragm **41** is molded in this way, it also tends to remain in the filled-chamber position, in other words, when the diaphragm **41** is bulging convexly outward from the cassette. This convex, filled-chamber position can be made unstable by adding additional material on the outer, usually concave surface of the  
10 diaphragm **41**. This additional material **43** can be seen in the cross-section of a preferred embodiment of the diaphragm as shown in FIG. 15. The diaphragm **41** shown in FIG. 15 is molded in the position shown and has a tendency to remain in that position. When the chamber is filled with fluid, the normally concave side of the diaphragm becomes convex, and the additional material **43** is subject to an additional amount of strain since it is at the  
15 outer radius of this convex, filled-chamber position. The diaphragm **41** shown in FIG. 15 also includes an integrally molded O-ring **44** around its circumference for mounting and sealing the diaphragm **41** in the cassette. FIG. 16 shows a view of the exterior side of the diaphragm **41** of FIG. 15. This surface of the diaphragm **41** is normally concave when the diaphragm is in the empty-chamber position. The additional material **43** can be seen in  
20 the view of FIG. 16. FIG. 17 shows the interior side of the diaphragm **41** of FIG. 15. This side is normally convex when the diaphragm **41** is in the empty-chamber position. Thus, as a result of molding the diaphragm so that its inner surface has a smooth constant radius and the outer surface has additional material, which thereby interrupts the smoothness and constant radius of the rest of the outer face of the diaphragm, the  
25 diaphragm **41** has the desired tendency to remain in the empty-chamber position while being unstable in the filled-chamber position.

By positioning this additional material **43** near the outlet mouth **57** of the pressure-conduction chamber **50**, the collapse of the diaphragm **41** from its filled-chamber can be somewhat controlled so that the diaphragm tends to collapse first in the lower portion of  
30 the pressure-conduction chamber near the outer mouth **57** before further collapsing in the upper region of the pressure conduction chamber nearer the inlet mouth **56**. The cassette

is preferably mounted in the control unit with a slight tilt so that the passage 36 is vertical and the inlet mouth 56 is at the very top of the chamber 50 and the outlet mouth 57 is at the very bottom of the chamber 50. This orientation permits the bubbles that may be present in the chamber 50 to gravitate towards the inlet mouth 56, which is at the top of the chamber. In a preferred method of eliminating the bubbles from the IV fluid, as described in the above-referenced, concurrently filed application for "Intravenous-Line Air-Elimination System," any bubbles that are detected by the control unit in the pressure conduction chamber 50 are forced by pressure from the control unit against the external surface of the membrane 41 up to the inlet mouth 56 to the cassette inlet 31 up the IV line to the fluid source, sometimes after several purging and filling cycles. When purging the bubbles from the chamber 50 through the inlet mouth 56 it is preferred that the chamber collapse at its bottom first so that the membrane does not interfere with bubbles moving upwards through the chamber 50.

Thus, the additional material 43 creates an instability in the membrane 41 when the membrane is in the filled-chamber position, thereby making the membrane more likely to collapse from the filled-chamber position than a membrane that did not have the additional material. The additional material 43, however, does not create an instability in the membrane 41 when the membrane is in the empty-chamber position. In many situations it is desirable to be able to introduce some instability into the membrane when the membrane is in the empty-chamber position. By introducing such instability into the membrane, less negative pressure is needed to move the membrane from its empty-chamber position.

To create an instability in the empty-chamber position, a pressure-relief tab 143 may be added to the membrane 141 as shown in FIG. 26. The pressure-relief tab 143 extends from the exterior surface 145 near the edge of the membrane 141, as can be seen in the cross-sectional view of FIG. 29. FIG. 28 shows another cross-sectional view, which view does not pass through the pressure-relief tab 143, and FIG. 27 shows a front view of the membrane 141. The tab 143 may be actuated by an actuator 149 (shown in FIG. 30) mounted in the control unit. When it is desired to introduce instability into the membrane--which will typically be whenever it is desired to fill a previously empty chamber 50--the actuator 143 forces the tab 143 towards the O-ring 144. This action pulls

the portion of the membrane **141** near the tab **143** away from the cassette's rigid wall, which partially defines the pressure-conduction chamber **50**. The tab **143** is located near the inlet mouth of the chamber **50** so that, when the actuator **149** pulls a portion of the membrane **141** away from the rigid wall, a pocket of space is formed into which the fluid  
5 can flow. By supplying a negative pressure to the exterior surface **145** of the membrane **141**, the control unit may cause more liquid to be drawn into the pressure-conduction chamber **50**. Less negative pressure is needed to move the membrane **141** out of the empty-chamber position, when the actuator **149** has urged the tab **143** towards the O-ring **144** and the rigid portion **117** of the cassette adjacent the tab **143**.

10 If it is desired to make the membrane **141** stable in the empty-chamber position, the control unit may cause the actuator **149** to be returned to the non-actuating position, so that the tab **143** may return to its normal position, extending outwardly from the cassette. As noted above, when the membrane is in the empty-chamber position, IV fluid may flow through the pressure-conduction chamber **50** through a conduit defined by raised portion  
15 of the rear wall (see FIGS. 3, 5 and 6) and leading from the inlet mouth of the pressure-conduction chamber **50** to the outlet mouth of the pressure-conduction chamber.

The pressure-reduction tab **143** also creates an instability in the filled-chamber position. When the pressure-conduction chamber **50** is filled with liquid, the exterior surface **145** of the membrane **141** becomes convex, rotating the tab **143** towards the O-  
20 ring **144**, so that the tab **143** is urged against the rigid portion **117** of the cassette. In this position, the tab **143** creates pressure on a portion of the membrane **141** so as to make the membrane less stable in the filled-chamber position so that the control unit needs to create less positive pressure to collapse the membrane **141** from its filled-chamber position.

FIG. 31 shows a cassette **215** that may be used in a bed-side pharmacy system,  
25 such as that described in the concurrently filed patent application for "System, Method and Cassette for Mixing and Delivering Intravenous Drugs" bearing attorney docket number 1062/B52, assigned serial no. 08/916,890, and which lists Kamen, Grinnell, Mandro, Gilbreath, Grant, Demers, Larkins and Manning as inventors, now abandoned in favor of continuation-in-part application, assigned serial no. 09/137,025 which application  
30 is incorporated herein by reference. Such a cassette may also use a membrane **241** having

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a pressure-reduction tab **243**, which creates some instability in the filled-chamber position and which may be actuated to create some instability in the empty-chamber position.

Returning to the cassette **15** shown in FIGS. 1-3, a preferred membrane design for the second membrane-based valve **7** is shown in FIGS. 18 and 19. This membrane has an O-ring **78** for mounting and sealing the inlet; membrane onto the cassette (like the lip **44** on the membrane **41** for the pressure-conduction chamber, and like the circular membrane, which is not shown, for the first membrane-based valve **6**). This membrane has a first portion **71**, which is used to seal off the inlet mouth **73** located on protrusion **72** (see FIG. 5). The control unit **10** exerts a pressure against this portion of the membrane **71** mechanically, in order to close off the valve **7**. A second compliant portion **74** of the membrane is sufficiently compliant so that when the control valve **2** is sufficiently restricting flow out of the outlet **76** of the second membrane-based valve **7**, the compliant portion **74** of the membrane will expand outwardly so as to hold, under pressure, a volume of IV fluid. This design is desirable so that when the inlet mouth **73** is closed, because the pressure-conduction chamber needs to be refilled, the fluid stored in the valving chamber (item **75** in FIG. 5) is available to be dispensed through the control valve **2**.

FIG. 20 shows a schematic for an electrical model of the operation of the second membrane-based valve **7** working in conjunction with the stopcock-type control valve **20**. When the valve leading from the outlet **57** of the pressure-conduction chamber **50** is open, permitting flow from the pressure-conduction chamber through valve **7**, and if the stopcock valve **20** is set to provide a large amount of resistance to the flow from valve **7** to the patient, the valving chamber **75** and its corresponding compliant membrane portion **74** can accumulate a "charge" of fluid, much like a capacitor, as shown in FIG. 20. When first portion **71** is then urged against inlet mouth **73** closing off flow from the pressure-conduction chamber **50**, the charge of fluid in the valving chamber **75** is urged by the compliant membrane portion **74** to continue flow through the stopcock valve **20**. As fluid exits the valving chamber **75**, the pressure of the fluid decreases as the compliant portion **74** of the membrane returns to its unstretched state. FIG. 21 shows a graph depicting the pressure of the IV fluid being delivered to a patient over time as outlet valve **71**, **73** is

closed at time  $t_1$  and reopened at  $t_2$ . A solid line depicts the pressure to the patient without a compliant membrane portion **74** design. With a compliant membrane portion **74**, the sharp drop off in pressure at  $t_1$  is eliminated or ameliorated. If the stopcock valve is nearly closed so that only a small trickle of fluid is allowed to flow through it, the design  
5 of the compliant membrane portion **74** will greatly smooth out the delivery of fluid, as long as the time between  $t_1$  and  $t_2$  is not too long. When the stopcock valve **2** is fully open a sharp drop in pressure may still be expected at time  $t_1$ .

As noted above (and as described in the above-referenced U.S. Patent No. 5,713,865, entitled "Intravenous-Line Air-Elimination System"), when an air bubble is  
10 being purged from the pressure-conduction chamber **50**, it is preferably forced up through the chamber's inlet valve **56** (which in this air-elimination mode is acting as an outlet). Preferably, the inlet port **56** is shaped so that a small bubble will not tend to stick to an edge of the port while allowing liquid to flow past it. To prevent such sticking of a small bubble, the port **56** preferably flares out so that the corner where the port **56** meets the  
15 inner wall of the pressure-conduction chamber **50** is greater than  $90^\circ$ , making the corner less likely a place where the bubble will stick. However, the mouth of the port **56** cannot be so large that liquid can easily flow by the bubble when fluid is exiting the pressure-conduction through the port **56**. In order to accomplish this, the port must be sized and shaped so that the surface tension of the IV fluid being forced upward from the pressure-  
20 conduction chamber **50** forces a bubble located at the port **56** up through the inlet valve **6**. It is also preferable that the port **56** be sized and shaped so that when liquid is pulled back into the pressure-conduction chamber **50**, the bubble can hover near the port as liquid passes around it. A preferred inlet port **56** shape is shown in FIGS. 22 and 23. The port's size increases from the end **57** that connects to the IV line's upper portion to the end  
25 **58** leading into the pressure-conduction chamber. FIG. 24 shows a cross-section of the inlet valve **56**. It has been found that providing an inlet port to the pressure-conduction chamber with this shape improves the air-elimination system's ability to purge bubbles from the chamber. Using a port such as that shown in FIGS. 22-24 in conjunction with the membrane **41** of FIGS. 15-17 helps force bubbles more quickly out of the pressure-  
30 conduction chamber when attempting to purge the bubbles back through the cassette's inlet **31** to the IV source.

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FIG. 25 shows a preferred arrangement of teeth around the circumference **29** of the control wheel **20**. The teeth provide means for a gear in the control unit **10** to engage securely the control wheel's circumference--in particular, a gear that is used to prevent the free flow of fluid through the cassette when the cassette is removed from the control unit

5 **10**. When the door **102** of the control unit **10** is being opened, the gear turns the control wheel **20** to close the stopcock-type valve **2**, thereby stopping all flow through the cassette and preventing free flow. To ensure that the gear does not continue turning the wheel **20** once the valve **2** has been closed off entirely, a sector **92** along the wheel's circumference is left free of teeth. When the wheel **20** is turned enough so that the gear is

10 adjacent this toothless sector **92**, the valve **2** is fully closed. The lack of teeth prevents the gear from continuing to turn the wheel; thus, the wheel cannot be turned too much.

Although the invention has been described with reference to several preferred embodiments, it will be understood by one of ordinary skill in the art that various modifications can be made without departing from the spirit and the scope of the

15 invention, as set forth in the claims hereinbelow.